

AMENDMENTS TO THE DRAWINGS

Please replace FIGURE 4 with amended FIGURE 4, as attached hereto, wherein reference numeral 110 has been added.

Please add FIGURES 5A, 5B, and 5C, as attached hereto, wherein alternate features described in the specification as filed, and claimed, have been depicted therein.

REMARKS

Examiner has objected to the drawings under 37 CFR 1.83(a), stating that "the drawings must show every feature of the invention specified in the claims." Specifically, Examiner objects to "the buckle of claim 6, the snap of claim 7, the clasp of claim 8, the magnet of claim 9, the electronic data collection instrumentation of claim 15, and the linked segments of claim 16." In response, Applicant has amended FIG. 4 to identify the electronic data collection instrument depicted therein, and has amended reference thereto on page 14 on the specification. Additionally, Applicant has added new drawing FIGS. 5A, 5B, and 5C to depict previously described features, and has amended the specification to include reference to said Figures.

Examiner has objected to the disclosure "because Applicant has used 35 U.S.C. 112, sixth paragraph, means-plus-function language to define features of the claimed invention," and Examiner has rejected Claims 1-16 under 35 U.S.C. 112, "as being indefinite for failing to set forth the supporting structure, material, or acts corresponding to means-plus-function." In response, Applicant has amended paragraph 2, page 12 and paragraph 2, page 16 of the specification, and respectfully traverses Examiner's rejection.

Applicant respectfully notes that the disclosure does explicitly define each said feature, offering preferred and

alternate forms. Page 12, lines 16-17 states "wherein strap fastening means 34a and 34b is preferably hook and loop fastener," and lines 20-25 state that "Preferably, cooperative fastening means 36 is hook and loop fastener, however, one skilled in the art would readily recognize that other types of cooperative fastening means could be utilized such as, for exemplary purposes only, buckles, snaps, magnets, clasps or loops." Further, page 16, lines 5-7 describe "an external negative pressure means such as, for exemplary purposes only, a vacuum or air pump." Thus, in each case specific disclosure was included for the supporting structure or material. Nonetheless, Applicant has amended paragraph 2, page 12 and paragraph 2, page 16 of the specification, replacing "strap fastening means 34a and 34b" with "strap fasteners 34a and 34b," "cooperative fastening means 36" with "cooperative fastener 36," and "external negative pressure means" with "external negative pressure device," and asserts that Examiner's rejection is rendered moot.

Examiner has rejected Claims 1-5 and 10-11 under 35 U.S.C. § 102(b) as being anticipated by *Wirtz* (4,657,003). Specifically, Examiner has stated that *Wirtz* ('003) discloses "sealing means 94" and "valve 25," and that the *Wirtz* ('003) configuration is "fully capable of maintaining air pathway clearance." In response thereto, Applicant has amended Claim 1 and respectfully traverses Examiner's rejection.

Applicant respectfully asserts that the *Wirtz* ('003) device is

NOT capable of maintaining air pathway clearance as defined in Applicant's specification. See, e.g., page 2, lines 8-10 "wherein a generally negative pressure is created on the exterior surface of a user's neck, thereby effectively holding open the air pathways;" page 5, lines 8-10 "by creating a negative pressure on the exterior surface of the neck, thereby drawing the neck out and holding air passages open;" and page 5, lines 16-22 "wherein a seal is provided proximate to the peripheral edge of the device enabling formation of a substantially airtight zone between the device and the neck of a user, and wherein a valve is provided to allow the escape of air from the airtight zone when neck tissues impinge into it during exhalation, thus enabling the creation of a negative pressure or vacuum, thereby effectively drawing open the air passages of a user."

Wirtz ('003) does teach a neck-worn device, however, Applicant respectfully asserts that *Wirtz* ('003) does not utilize, anticipate, teach or render obvious a neck worn device that delivers negative pressure on the exterior surface of the neck in order to hold air passages open. First, the valve of *Wirtz* ('003) "functions to evacuate the INTERIOR of the bag." Col. 6, lines 23-24. This is entirely unlike Applicant's valve, which functions to evacuate a defined area on the EXTERIOR of the device. It is this functionality that is critical to the performance of Applicant's device. There is no provision or description of any possibility that *Wirtz* ('003) could be able to function in such a way.

In addition to the distinction in the functionality of the valve, the referenced "sealing means 94" of *Wirtz* ('003) is distinguished as a "sheet of cushioning material," Col. 9, line 26. Even if the *Wirtz* ('003) valve were repositioned and reconformed to enable the evacuation of air from the exterior surface in lieu of the interior of the device, it would still be unable to function as Applicant's device because the *Wirtz* ('003) cushioning material does not form a seal in order to define a "generally airtight zone" between the device and the user's neck. *Wirtz* ('003) is merely a self-described immobilizer device with cushioning provided for comfort. This is unlike Applicant's device in both structure and function. Applicant's device does not "restrain" a body portion, but is intended to enable as much movement of the neck as possible. The focus of Applicant's device is the ability of the valve to automatically adjust to the pressure differential between the ambient air and the air space in the compartment between the device and the neck of the wearer, such that as the patient suffers the onset of apnea and breathes more deeply, with increased movement of the confined portion of the neck, an increase in the vacuum results, creating a pulling force on the airways, forcing them to remain open.

Applicant has amended Independent Claim 1 to clarify and more succinctly define that Applicant's seal is defined proximate the peripheral edge of the inner surface of the support member, defining an air compartment between said inner surface and the neck of the user, and that Applicant's valve enables the exit of air from "said

air compartment between said inner surface of said support member and the neck of a user. Because "a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference," *Verdegaal Bros. V. Union Oil co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987), because "the identical invention must be shown in as complete detail as is contained in the...claim," *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989), and because *Wirtz* ('003) does not describe each and every element of Applicant's device, nor the identical invention, Applicant believes that Applicant's Independent Claim 1, as amended, is distinguished over *Wirtz* ('003).

Examiner has rejected Claims 6-9 and 16 under 35 U.S.C. § 103(a) as being unpatentable over *Wirtz* ('003) in view of *Calabrese* ('052), Claims 12, 17-18, and 20 under 35 U.S.C. § 103(a) as being unpatentable over *Wirtz* ('003) in view of *Visness et al.* (6,494,854), Claims 13-15 under 35 U.S.C. § 103(a) as being unpatentable over *Wirtz* ('003) in view of *Sackner* (4,452,252), and Claim 19 under 35 U.S.C. § 103(a) as being unpatentable over *Wirtz* ('003) in view of *Visness et al.* ('854) and further in view of *Sackner* ('252). In response, Applicant has amended independent Claims 17 and respectfully traverses Examiners rejection.

As discussed above, *Wirtz* ('003) does not teach or suggest a defined compartment between the inner surface of the device and the neck of the wearer, nor a valve enabling the evacuation of air

therefrom. Nor are such features or embodiments taught or suggested by *Calabrese* ('052), *Visness et al.* ('854), or *Sackner* ('252). "To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art," *In re Royka*, 490 F.2d 981 (CCPA 1974); thus, Applicant respectfully asserts that the amended Independent Claims 1 and 17 are not obvious. Further, because "[i]f an independent claim is nonobvious under 35 USC 103, then any claim depending therefrom is nonobvious," *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1985), remaining dependent Claims 2-16 and 18-20 are also not obvious.

"A different situation exists where the solution is obvious from prior art which contains the same solution for a similar problem," *In re Wiseman*, 596 F.2d 1019, 1022 (CCPA 1979) (emphasis in original); however, such is not the case with the references cited. None of the cited references, *Wirtz* ('003), *Calabrese* ('052), *Visness et al.* ('854), or *Sackner* ('252), suggest the desirability of an automatically adjustable vacuous compartment defined between the outer surface of a neck worn device and the neck of the wearer in order to force air pathways to remain open. None of the references seek a solution to a similar problem, that is, the inability of a sleep apnea sufferer to breathe consistently. Further, none of the references offer any possible solution to Applicant's defined problem.

"The teaching or suggestion to make the claimed combination and

the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure." *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991). Even if *Wirtz* ('003), *Calabrese* ('052), *Visness et al.* ('854), and *Sackner* ('252) are combined, one does not arrive at Applicant's invention. Moreover, modifying any of the references, as suggested by Examiner, would change the principle of operation of each of the inventions described. "If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810 (CCPA 1959).

Applicant believes that the foregoing amendments and arguments distinguish the claims over the prior art and establish that Applicant's claimed invention is novel and non-obvious, thereby placing the rejected independent claims 1 and 17 and all remaining depending claims in condition for allowance.

CONCLUSION

The above amendments are corrections to form and thus, no new matter was added. In light of the above amendments and arguments, Applicant respectfully believes that Claims 1-20 are now allowable. Should there be any questions or concerns, the Examiner is invited to telephone Applicant's undersigned attorney.

Respectfully submitted, this 2nd day of March, 2005.



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